In re Appln. No.: 05/419,305

REMARKS

The Office Action has been carefully reviewed. No claim is allowed. Claim 1 presently appears in this application and defines patentable subject matter warranting its allowance. Reconsideration and allowance are hereby respectfully solicited.

Claim 1 has been objected to because of informalities. Appropriate correction is made, thereby obviating this objection.

Claim 1 has been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for the enzyme of SEQ ID NO:1 or enzymes encoded by genes which hybridize to SEQ ID NO:2 under specific conditions, does not reasonably provide enablement for any enzyme with the claimed properties.

The examiner indicates that applicant' arguments are not persuasive because, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc., are well known to the skilled artisan, producing variants as claimed requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. The examiner further states that without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities which would clearly constitute undue experimentation. This rejection is respectfully traversed.

In re Appln. No.: 09/419,305

Applicants submit that it would not be necessary for a skilled artisan to produce all the possible variants of the amino acid sequence of SEQ ID NO:1. It is not necessary for a skilled artisan to find out all the variants that satisfies the definition as recited in claim 1. What is expected of a skilled artisan is to produce a finite number of variants using conventional methods and to screen them in accordance with their properties, such as defined in claim 1. As the examiner states, the methods for obtaining variants of a known sequence are well known to a skilled artisan. The methods to test the variants to see if they have the physicochemical properties as recited in claim 1 are well described in Experiment 2 at pages 13 to 19 of the specification. It is therefore believed that the specification provides sufficient enablement for an enzyme with the claimed properties.

The examiner states that the specification does not establish: (A) regions of the protein structure which may be modified without affecting activity and thermostability; (B) the general tolerance of such enzymes to modification and the extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function. Applicants however do not believe that (A) to (C) are indispensable for providing enablement.

With due respect to the examiner, applicants point out that a skilled artisan can find out at least one variant having the physicochemical properties as recited in claim 1 even if a

In re Appln. No.: 09/419,305

skilled artisan is not aware of (A) to (C) at all, because the methods for producing variants and the method for screening them in accordance with their physicochemical properties are well known and well described in the specification. This means that the disclosure of the amino acid sequence of SEQ ID NOs:1, 3, and 4, and the physicochemical properties open the way for a skilled artisan to obtain a variant having the physicochemical properties as recited in claim 1. It is therefore believed that claim 1 is sufficiently enabled by the specification and therefore should be allowed.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claim comply with 35 U.S.C. \$112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

Claim 1 has been amended as follows:

1(Four times-amended). A purified recombinant thermostable enzyme which is obtained by the recombinant DNA technology and which has the following physicochemical properties:

- (1) Action
 - Forming non-reducing saccharides having a trehalose structure as an end unit and having a degree of glucose polymerization of at least 3 from maltotetraose or reducing amylaceous saccharides having a degree of glucose polymerization of at least 3;
- (2) Molecular weight

 About 69,000-79,000 daltons on sodium dodecyl

 sulfate polyacrylamide gel electrophoresis (SDS-PAGE);
- (3) Isoelectric point (pI)
 About 5.4-6.4 on isoelectrophoresis;
- (4) Thermostability

 Substantially not inactivated even when incubated in an aqueous solution (pH 7.0) at 85°C for 60 min.; and
- (5) Amino acid sequence
 An amino acid sequence which is not identical to
 SEQ ID NO:1 but which has physicochemical

In re Appln. No.: 09/419,305

properties of (1) to (4) inherent to a thermostable enzyme of SEQ ID NO:1, said amino acid sequence comprising the sequence of at least two contiguous amino acid residues in SEQ ID NO:3 and/or SEQ ID NO:4.